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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,879	05/10/2006	Earl M. Zergiebel	2909 US	2518
50855	7590	09/20/2007		
COVIDIEN 60 MIDDLETOWN AVENUE NORTH HAVEN, CT 06473			EXAMINER WISTERMAYER, ALEXIS M	
			ART UNIT	PAPER NUMBER
			3709	
			MAIL DATE	DELIVERY MODE
			09/20/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/560,879

Applicant(s)

ZERGIEBEL, EARL M.

Examiner

Alexis M. Wistermayer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/02/07, 2/2/07, 2/1/06</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 recites the limitation "said center shaft" in line 1. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9 and 12-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Sanders et al (US PGPub 2003/0158555).

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Regarding Claim 1: Sanders et al. teach an absorbable screw fastener/surgical screw system a body portion/shank having a proximal end, a distal end, the body portion/shank being threaded (Paragraph 29), and the head portion having a driver receiving structure (Paragraph 30). The diameter of the head is roughly/substantially equal to the widest diameter of the body portion/shank (Paragraph 97).

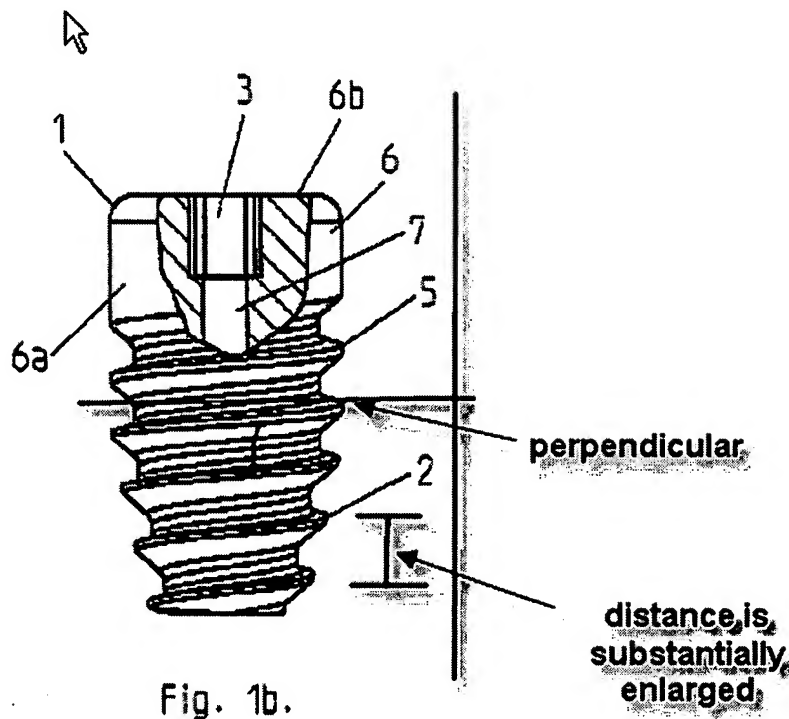
Regarding Claim 2: Sanders et al. teach a center shaft/central bore that is tapered from a narrow distal end to a narrow proximal one (Paragraph 29 and 94).

Regarding Claims 3 and 4: Sanders et al. teach a driver receiving structure that has a substantially flattened surface (Figure 1b, the top of the screw head indicated by 6b).

Regarding Claim 5: Sanders et al. teach a device where the fastener is formed of PGA/PLA and PGA (Paragraphs 37, 39, and 41).

Regarding Claim 6: Sanders et al. teach a fastener where the distal end is blunt (the very bottom of the screw shown in Figure 1c).

Regarding Claims 7 and 8: Sanders et al. teach a fastener where the land of the thread is substantially perpendicular to the longitudinal axis and where a distance of the thread is substantially enlarged (please see drawing below).



Regarding Claim 9: Sanders et al. teach a fastener which has a minimum head portion diameter of 3.5 mm and a maximum head portion diameter of 4.5 mm (Paragraph 107).

Regarding Claim 12: Sanders et al. teach a fastener including a lumen/central bore extending through an entire length thereof (Figure 1c Element 7).

Regarding Claim 13: Sanders et al. teach a fastener with a body portion having a circular cross-section (Figure 1a Element 2).

Regarding Claim 14: Sanders et al. teach a method of inserting an absorbable screw fastener/surgical screw system (Paragraph 106).

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Claims 23-27, 29, and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Sanders et al (US PGPub 2003/0158555).

Regarding Claim 23: Sanders et al. teach a body portion/shank having a proximal and distal end, a threaded portion, and a head portion having driver receiving structure formed therein (Paragraphs 29 and 30). The diameter of the head is roughly/substantially equal to the widest diameter of the body portion/shank (Paragraph 97).

Regarding Claim 24: Sanders et al. teach a fastener where the driver receiving structure further defines a slot/recess (Paragraph 98).

Regarding Claim 25: Sanders et al. teach a fastener where the slot/bore (Figure 1c Element 7) extends the entire length of the screw fastener.

Regarding Claim 26: Sanders et al. teach a device where the fastener is formed of PGA/PLA and PGA (Paragraphs 37, 39 and 41).

Regarding Claim 27: Sanders et al. teach a distal end of the body portion/shank defining a distal surface that is angled with respect to the longitudinal axis (Figure 1a).

Regarding Claim 29: Sanders et al. teach a head portion that defines a distal surface that is angled with respect to the longitudinal axis (Figure 1b Element 6a).

Regarding Claim 32: Sanders et al. teach a slot formed in each thread that includes at least one of a radiused leading edge and a radiused trailing edge (Figure 1a Element 5).

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15, 16, and 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Gotfried (US Pat 5429641).

Regarding Claim 15: Gotfried teaches an instrument comprising: a distal portion having an elongated outer tube/shaft (Figure 11 Element 47), a proximal portion having a trigger mechanism (Figure 11 Elements 48 and 50, Column 6 lines 40-50), and a driver/torque subassembly in the outer tube and movable relative to the outer tube (Figure 11 Element 42).

Regarding Claim 16: Gotfried teaches an outer tube/shaft having a crenulated tip (Figure 11 Element 44).

Regarding Claim 18: Gotfried teaches an instrument where the driver/torque subassembly defines two flexible tabs (Figure 11 Elements 45 and 49, since all materials have *some* degree of flexibility to them).

Regarding Claim 19: Gotfried teaches an outer tube being biased to a distally advanced position (Figure 11 Element 47).

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Regarding Claim 20: Gottfried teaches a pilot disposed within the outer tube, having a tapered surface (Figure 11 Element 41).

Regarding Claim 21: Gottfried teaches an instrument comprising a fastener retainer (Figure 11 Element 43).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanders et al. (US PGPub 2003/0158555) as applied to Claim 1 above.

Regarding Claims 10 and 11: Sanders et al. teach a similarly disclosed device as described in the rejections above. Sanders et al. do not teach a height of a head portion of 1.5 mm nor a length of a body portion of 5 mm. At the time of the invention, it would have been obvious to one having ordinary skill in the art to use these dimensions in Sanders et al.'s device, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). The



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motivation would have been to offer the optimal sizes for patients (using a smaller screw size for a child, for instance). Please see MPEP § 2144.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gotfried (US Pat 5429641) as applied to Claim 15.

Gotfried discloses a similar device as described in the rejections above. Gotfried does not teach a trigger mechanism that comprises a ratchet mechanism. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to use a ratchet mechanism in Gotfried's device. Official Notice is taken that a ratchet mechanism could be used in Gotfried's instrument as an equivalent and alternative means of inserting the absorbable screw fastener.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gotfried (US Pat 5429641) in view of Sanders et al (US PGPub 2003/0158555).

Gotfried teaches an instrument having an outer tube on a distal end and a trigger mechanism (Figure 11 Elements 47, 48, and 50). Gotfried does not teach an absorbable screw fastener. However, Sanders et al. teach an absorbable screw fastener/surgical screw system having a body portion/shank and a head portion (Paragraph 29). Gotfried and Sanders et al. are analogous art because they are from the same field of endeavor of orthopedic devices. At the time of the

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invention, it would have been obvious to a person of ordinary skill in the art to use Sanders et al.'s screw fastener with Gotfried's instrument. The motivation would have been to offer an alternative and equivalent means of having both the inserter instrument and the screw fastener configured to fit together.

Claims 28, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanders et al (US PGPub 2003/0158555).

Regarding Claims 28, 30, and 31: Sanders et al. teach the device as rejected in Claims 23-27, 29, and 32 above. Sanders et al. does not teach angle measurements for the head portion or body portion of the fastener. At the time of the invention, it would have been obvious to one having ordinary skill in the art to construct these angle measurements in Sanders et al.'s device with respect to the longitudinal axis to be between 5 and 15 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexis M. Wistermayer whose telephone

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number is 571-272-1197. The examiner can normally be reached on Monday - Friday 8 am - 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMW 9/17/07



MARK EASHOO, PH.D.  
SUPERVISORY PATENT EXAMINER

17/Sep/07